

CLEOCIN HCL- clindamycin hcl 300mg capsule
Advanced Rx Pharmacy of Tennessee, LLC

Clindamycin HCl 300mg capsules

Dosage and Administration Section

DOSAGE AND ADMINISTRATION

If significant diarrhea occurs during therapy, this antibiotic should be discontinued (see BOXED WARNING).

Adults: Serious infections—150 to 300 mg every 6 hours. More severe infections - 300 to 450 mg every 6 hours.

Pediatric Patients (for children who are able to swallow capsules): Serious infections - 8 to 16 mg/kg/day (4 to 8 mg/lb/day) divided into three or four equal doses. More severe infections - 16 to 20 mg/kg/day (8 to 10 mg/lb/day) divided into three or four equal doses. Clindamycin should be dosed based on total body weight regardless of obesity.

To avoid the possibility of esophageal irritation, clindamycin hydrochloride capsules should be taken with a full glass of water.

Clindamycin hydrochloride capsules are not suitable for children who are unable to swallow them whole. The capsules do not provide exact mg/kg doses therefore it may be necessary to use the clindamycin palmitate oral solution in some cases.

Serious infections due to anaerobic bacteria are usually treated with clindamycin injection. However, in clinically appropriate circumstances, the physician may elect to initiate treatment or continue treatment with clindamycin hydrochloride capsules.

In cases of β -hemolytic streptococcal infections, treatment should continue for at least 10 days.

Indications and Usage Section

INDICATIONS AND USAGE

Clindamycin hydrochloride capsules, USP are indicated in the treatment of serious infections caused by susceptible anaerobic bacteria.

Clindamycin hydrochloride capsules, USP are also indicated in the treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. Because of the risk of colitis, as described in the BOXED WARNING, before selecting clindamycin, the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin).

Anaerobes: Serious respiratory tract infections such as empyema, anaerobic pneumonitis, and lung abscess; serious skin and soft tissue infections; septicemia; intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms resident in the normal gastrointestinal tract); infections of the female pelvis and genital tract such as endometritis, nongonococcal tubo-ovarian abscess, pelvic cellulitis, and postsurgical vaginal cuff infection.

Streptococci: Serious respiratory tract infections; serious skin and soft tissue infections.

Staphylococci: Serious respiratory tract infections; serious skin and soft tissue infections.

Pneumococci: Serious respiratory tract infections.

Bacteriologic studies should be performed to determine the causative organisms and their susceptibility to clindamycin.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of clindamycin hydrochloride capsules, USP and other antibacterial drugs, clindamycin hydrochloride capsules, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Principal Display Panel

* Each capsule contains clindamycin hydrochloride, USP equivalent to 300 mg of clindamycin.

DOSAGE AND USE: See accompanying prescribing information.


Store at 20° - 25° C (68° - 77° F) [See USP Controlled Room Temperature].

NDC 63304-693-01

Clindamycin Hydrochloride Capsules, USP

300 mg*

Rx only
100 Capsules

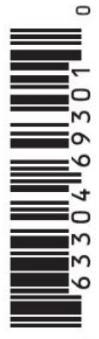


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CLEOCIN HCL

clindamycin hcl 300mg capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80425-0103(NDC:63304-693)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	300 mg

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	RX693
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0103-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065061	03/23/2001	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)**Establishment**

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0103)

Revised: 11/2020

Advanced Rx Pharmacy of Tennessee, LLC